Remarks

Status of the Claims

Claims 26-28, 30-33, 35, 37, 38, 40, and 41 have been amended. New claims 42 and 43 have been added. Claims 34 and 36 have been cancelled. Claims 1-25 were cancelled in the Preliminary Amendment. Claims 26-33 and 38-41 have been withdrawn from consideration. Claims 35, 37, 42, and 43 are presented for the Examiner's review and consideration. Applicants believe the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Amendments to the Specification

No new matter has been added by the amendment to the title made herein. The title has been amended only to define the acronym/abbreviation "ARP" as referring to an "acetylcholinesterase (AChE)-derived peptide." The ARP peptide is described throughout the specification as originally filed. *See* paragraphs **[0005]**; **[0007]**; and **[0020]** of the published application; U.S. Patent Application Publication 2007/0224181 A1; hereinafter "published application."

No new matter has been added by the amendments to paragraphs **[0020]**; **[0022]**; **[0023]**; **[0025]-[0027]**; **[0029]-[0031]**; **[0141]**; **[0153]**; **[0171]**; **[0174]**; **[0176]**; and **[0185]** made herein. These paragraphs were amended only to correct inadvertent typographical errors and to refer to the sequence identification numbers in the preferred format. For example, the format "SEQ ID NO:1" rather than the originally-filed format "SEQ. ID. NO. 1."

No new matter has been added by the amendments to paragraphs **[0033]**; **[0034]**; **[0215]**; and **[0226]** made herein. These paragraphs were amended only to provide sequence identification numbers for sequences mentioned therein such that these sequences can be identified in the Sequence Listing.

No new matter has been added by the amendments to Tables 1 and 2 made herein. The

tables were amended only to refer to the sequence identification numbers in the preferred format. For example, the format "SEQ ID NO:1" rather than the originally-filed format "SEQ. ID. NO. 1."

Amendments to the Claims (including both pending and withdrawn)

No new matter has been added by the amendments to claims 26-28, 30-33, 35, 37, 38, 40, and 41 made herein. These claims were amended to correct inadvertent typographical errors and to refer to the sequence identification numbers in the preferred format. For example, the format "SEQ ID NO:1" rather than the originally-filed format "SEQ. ID. NO. 1."

Several of these claims have been further amended as follows:

Claims 26, 35, and 37 have been amended to define the acronym/abbreviation "AChE-derived peptide" as referring to an "acetylcholinesterase (AChE)-derived peptide." The AChE-derived peptide is described throughout the specification as originally filed. *See* paragraphs **[0005]**; **[0007]**; and **[0020]** of the published application.

Claim 35 has been amended to specify that the AChE-derived peptide referred to is SEQ ID NO:1. *See* paragraph **[0020]** of the published application.

Claim 37 has been amended to clarify the claimed method by including the following steps: isolating immature cells from the blood obtained from the subject; contacting the immature cells with an AChE-derived peptide (SEQ ID NO:1); and introducing the cells in a subject after the cells are contacted by the peptide. The method is described throughout the specification as originally filed. *See* paragraphs **[0027]**; **[0176]**; **[0177]**; **[0195]-[0200]**; Example 23; and Example 24 of the published application.

No new matter has been added by the addition of claims 42 and 43 made herein. These claims have been added to clarify that cells introduced in step d) of the method recited by claim 37 can be introduced into the same subject from which the cells were initially isolated (claim 42) or in a different subject (claim 43). This concept is supported by the specification as originally filed. *See* paragraphs **[0182]-[0184]**.

Drawings/Specification

A. Compliance with the Sequence Rules

The Examiner asserts that the instant application is not fully compliant with the requirements of 37 C.F.R. §1.821 through 1.825 (Sequence Rules) because Figures 1A-B show C-terminal amino acid sequences of AChE-S and AChE-R without corresponding sequence identification numbers.

In response, Applicants note that the sequences shown in Figures 1A-1B are included in the Sequence Listing as filed. Figure 1A shows SEQ ID NO:2; the C-terminal amino acid sequence unique to the human AChE-S variant. Figure 1B shows SEQ ID NO:1; the C-terminal amino acid sequence unique to the human AChE-R variant. Paragraphs **[0033]** and **[0034]** of the "Brief Description of the Drawings" have been amended herein to include the appropriate sequence identification numbers.

Accordingly, Applicants respectfully submit that the instant application is now in compliance with 37 C.F.R. §1.821 through 1.825 and thus request reconsideration and withdrawal of this objection.

B. Objection to the Specification

The disclosure was objected to because the references to the sequence identifiers should be in the preferred format of "SEQ ID NO:" rather than "SEQ. ID. NO." as is used throughout the specification.

In response, the specification and claims have been amended herein to refer to the sequence identification numbers in the preferred format (SEQ ID NO:).

Accordingly, Applicants respectfully request reconsideration and withdrawal of this objection to the specification.

Objections to the Claims

Claims 34 and 37 were objected to for informal formatting of the sequence identification

numbers, *i.e.* the format "SEQ. ID. NO." was used rather than the preferred "SEQ ID NO:" format.

Claim 34 has been cancelled, thus rendering the objections moot regarding claim 34.

As noted above, the claims, including claim 37, have been amended herein to refer to the sequence identification numbers in the preferred format.

Claims 34 and 37 were additionally objected to for using an acronym without first defining the acronym.

Claim 37 has been amended herein to define the acronym "AChE-derived peptide" as referring to an "acetylcholinesterase (AChE)-derived peptide." The AChE-derived peptide is described throughout the specification as originally filed. *See* paragraphs **[0005]**; **[0007]**; and **[0020]** of the published application.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the objection to the claims.

Rejection under 35 U.S.C. §112, second paragraph

Claims 34 and 37 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner asserts that the phrase "such as" renders the claims indefinite.

Claim 34 has been cancelled, thus rendering the rejection moot regarding claim 34.

Claim 37, as amended herein, does not include the phrase "such as."

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejections under 35 U.S.C. §112, first paragraph

Claims 34 and 37 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Examiner asserts that the claims are suggesting that complete inhibition or prevention of such diseases as any autoimmune

disease, inflammation, rheumatoid arthritis, multiple sclerosis, chronic stress *etc*. can be prevented by administering the AChE-derived peptide, however complete prophylaxis of such diseases is a standard that is unachievable and the specification, while suggesting treatment of said conditions might be possible, does not describe prevention.

Claim 34 has been cancelled, thus rendering the rejection moot regarding claim 34.

Claim 37, as amended herein, does not recite prevention of any condition.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection (enablement).

Claim 37 was further rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Examiner asserts that the claim is missing steps as it (the claim) reads on and is interpreted to treat the noted conditions by simply removing blood from a subject.

Claim 37 has been amended herein to clarify the claimed method by including the following steps: isolating immature cells from the blood obtained from the subject; contacting the immature cells with an AChE-derived peptide (SEQ ID NO:1); and introducing the cells in a subject after the cells have been contacted with the peptide. The method is described throughout the specification as originally filed. *See* paragraphs **[0027]**; **[0176]**; **[0177]**; **[0195]-[0200]**; Example 23; and Example 24 of the published application.

Considering that claim 37, as amended herein, includes contacting the immature cells obtained from the blood sample with an AChE-derived peptide and introducing the immature cells (after contact with the peptide) back into the subject from which the blood sample was extracted (or into a different subject), this claim now recites a method which would treat the conditions recited. *See* Examples 23 and 24 of the published application.

Accordingly, Applicants respectfully submit that the steps of the claimed method are now clarified and thus respectfully request reconsideration and withdrawal of this rejection (enablement).

Claim 34 was further rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a method of treating conditions wherein lymphocytic

activity is reduced by administering a therapeutically-effective amount of the AChE-derived peptide, allegedly does not reasonably provide enablement for such a method including administering a therapeutically-effective amount of the AChE-derived peptide or any functional fragments or derivatives thereof.

Claim 34 has been cancelled, thus rendering this rejection moot.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection (scope of enablement).

Claim 35 was rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a method of inducing a shift in the activity of lymphocytes *in vitro* or *ex vivo* utilizing the AChE-derived peptide of SEQ ID NO:1, does not reasonably provide enablement for using any AChE-derived peptide.

The Examiner admits that claim 35 is enabled for the use of SEQ ID NO:1 (page 14 of the current Office Action). Thus, claim 35 has been amended to recite only the AChE-derived peptide of SEQ ID NO:1.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection (scope of enablement).

Claims 34, 35, and 37 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner asserts that the standard and requirement for prevention has not been met. While Applicants might be in possession of a treatment, they have not described and are not deemed to be in possession of methods of preventing the noted conditions. Furthermore, regarding methods of treating using a large and variable genus of peptides of SEQ ID NO:1 including functional fragments and derivatives, the Examiner asserts that the specification describes only a single species (SEQ ID NO:1) which is not deemed representative of the whole genus.

Claim 34 has been cancelled, thus rendering the rejection moot regarding claim 34.

Claims 35 and 37, as amended herein, do not recite prevention of any condition.

The Examiner acknowledges that the inventors are in possession of SEQ ID NO:1 (page 16 of the current Office Action). Thus, claims 35 and 37 have been amended to recite only the

AChE-derived peptide of SEQ ID NO:1.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection (written description).

Rejection under 35 U.S.C. §102(b)

Claims 34-36 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Soreq et al. (U.S. Patent Application Publication 2003/0036632 A1; hereinafter "Soreq"). For reasons set forth below, Applicants respectfully submit that this rejection should be withdrawn.

Claims 34 and 36 have been cancelled, thus rendering the rejection moot regarding claims 34 and 36.

Soreq

Soreq discloses peptides derived from acetylcholinesterase, compositions containing the peptides, antibodies against the peptides, and methods for using the peptides in screening methods for drugs. *See* abstract and paragraph **[0002]**.

Instant Invention

The instant invention, as currently claimed in independent claim 35, provides, *inter alia*, a method for inducing a shift in the activity of lymphocytes *in vitro* or *ex vivo*. The method includes contacting the acetylcholinesterase (AChE)-derived peptide of SEQ ID NO:1 with the lymphocytes for a period of time. *See* paragraph **[0180]** and Example 24 of the published application.

Argument

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union*

Oil Co. of California, 814 F.2d 628, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). *See* MPEP 2131.

The Examiner alleges that Soreq discloses the claimed method at paragraph **[0288]** in which *in vitro* incubation of bone marrow cells with ARP induces a shift in the activity of lymphocytes.

Applicants respectfully disagree as to what paragraph **[0288]** actually teaches. As noted above, the claimed method involves contacting lymphocytes with SEQ ID NO:1. In paragraph **[0288]** Soreq refers to contacting bone marrow endothelial cells with ARP. Stem cells present in the bone marrow are the source of lymphocytes and not the endothelial cells as suggested by the Examiner.

Therefore, Soreq does not teach each and every element of the method as currently claimed. Accordingly, independent claim 35 is not anticipated by Soreq.

In light of the above, Applicants respectfully request reconsideration and withdrawal of this rejection.

Conclusion

In light of all the foregoing amendments and remarks this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

The fee for a one-month extension of time pursuant to 37 CFR §1.17(a)(1) in the amount of $130 is believed to be due and is being paid via credit card. No other fees are believed to be due at this time. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 7056-X08-023).

Respectfully submitted,
/Katharine F. Davis Wong/
Katharine F. Davis Wong, Reg. #51,598
For: Martin Fleit, Reg. # 16,900

Customer Number: 27317
Martin Fleit
FLEIT GIBBONS GUTMAN BONGINI & BIANCO
21355 East Dixie Highway, Suite 115
Miami, Florida 33180
Tel: 305-830-2600; Fax: 305-830-2605
e-mail: mfleit@fggbb.com